No. 17-71636

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, *et al.*,
Petitioners,

STATE OF NEW YORK, *et al.*,
Petitioner-Intervenors,

v.

ANDREW WHEELER, ACTING ADMINISTRATOR OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY; AND U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondents.

On Petition for Judicial Review of an Action by the U.S. Environmental Protection Agency

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MOTION OF CROPLIFE AMERICA FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* SUPPORTING RESPONDENTS' PETITION FOR *EN BANC* AND PANEL REHEARING

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October 4, 2018

Pursuant to Circuit Rule 29-2, CropLife America (CLA) respectfully requests leave to file a brief as *amicus curiae* in support of Respondents' petition for *en banc* and panel rehearing of this Court's August 9, 2018 opinion vacating an order of the U.S. Environmental Protection Agency (EPA) regarding pesticides containing the active ingredient chlorpyrifos and remanding to EPA with the direction to "revoke all tolerances and cancel all registrations for chlorpyrifos within 60 days." Slip Op. at 32. A copy of CLA's proposed brief accompanies this motion.

As required by Circuit Rule 29-3, CLA sought the parties' consent to file an *amicus* brief. Respondents do not oppose this motion. Intervenor State of New York takes no position on whether it would consent to CLA's participation as *amicus curiae*, and the remaining Intervenors have not provided their positions. Petitioners oppose this motion unless they can obtain the Court's approval to expand the page limit for their response to the petition for rehearing by an additional five pages.

CLA'S INTEREST

CLA is a non-profit trade association that represents companies that develop, register and sell pesticide products in the U.S. CLA's member companies produce most of the crop-protection and pest-management products regulated by EPA

under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended, 21 U.S.C. § 346a. CLA represents its members' interests by, among other things, monitoring federal agency actions and related litigation of concern to the crop-protection and pest-control industry, and participating in such actions as appropriate.

CLA has a direct and immediate interest in the Court rehearing the panel's decision. The panel's order directing EPA to revoke all tolerances and cancel all registrations of products containing chlorpyrifos would deprive CLA members of their right to manufacture and sell pest-control products containing this compound without any of the processes that FIFRA requires for such an action. CLA seeks leave to participate as *amicus curiae* to defend its members' important interests, which neither EPA nor any other party or *amicus* has yet represented in this case. The Court has not yet heard from representatives of the wide range of companies that develop, register and sell pesticide products, and no party has fully addressed the practical implications of removing chlorpyrifos from the marketplace. For these reasons, CLA has a substantial interest in this matter.

ARGUMENT

The Court's consideration of Respondents' petition will benefit from CLA's substantial experience with FIFRA's registration and cancellation processes and the consequences of cancelling a pesticide registration on both manufacturers and users. The rights of CLA's members are directly impacted by the panel majority's order. The Court should have information on the practical consequences that these companies and pesticide users will face if the panel opinion is not revised.

CLA regularly participates in litigation before this Court and district courts in this Circuit in cases raising issues involving FIFRA that impact the rights of CLA members. *E.g.*, *Nat'l Family Farm Coalition v. EPA*, No. 17-70810, Doc. ID 10946537, Dkt. No. 91-1 (July 18, 2018) (motion for leave to file *amicus* brief supporting respondents); *Ellis v. Housenger*, 252 F. Supp. 3d 800 (N.D. Cal. 2017) (as intervenor). CLA also participated, as *amicus curiae*, in previous litigation over the petition to revoke tolerances that is the subject of this case. *In re Pesticide Action Network N. Am.*, 840 F.3d 1014 (9th Cir. 2016). This experience puts CLA in the position to convey to the Court the ramifications of the panel majority's opinion.

CLA's proposed *amicus* brief offers case law and background information on FIFRA's cancellation process beyond what Respondents have addressed in their

petition. CLA's proposed brief describes in detail how this process works, how it protects CLA's members and other stakeholders, and how the panel majority's decision to forego this process will impact pesticide manufacturers and users. The proposed brief also discusses how the panel opinion improperly orders the cancellation of important public health and other non-food uses of chlorpyrifos. Finally, CLA will provide the Court with greater detail on EPA's ongoing, statutorily-mandated efforts to assess the continued registration of chlorpyrifos. By filing its brief, CLA seeks to "fulfill[] the classic role of amicus curiae by assisting in a case of general public interest, supplementing the efforts of counsel, and drawing the court's attention to law that escaped consideration." *Miller-Wohl Co. v. Comm'r of Labor & Indus.*, 694 F.2d 203, 204 (9th Cir. 1982).

CONCLUSION

For the foregoing reasons, CLA respectfully requests this Court to grant its motion for leave and accept the proposed *amicus* brief in support of Respondents' petition for *en banc* and panel rehearing.

Respectfully submitted,

October 4, 2018

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CERTIFICATE OF SERVICE

I certify that on October 4, 2018, I electronically filed a copy of the foregoing motion with the Clerk of Court for the U.S. Court of Appeals for the Ninth Circuit via the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/ Kathryn E. Szmuszkovicz
Kathryn E. Szmuszkovicz

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BRIEF OF *AMICUS CURIAE* CROPLIFE AMERICA IN SUPPORT OF RESPONDENTS' PETITION FOR *EN BANC* AND PANEL REHEARING

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CORPORATE DISCLOSURE STATEMENT

Amicus curiae CropLife America is a non-profit corporation. It has no parent corporation, and no publicly-held corporation owns 10% or more of its stock.

Dated: October 4, 2018

s/ Kathryn E. Szmuszkovicz
Kathryn E. Szmuszkovicz

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INTEREST OF *AMICUS CURIAE* AND SUMMARY

Amicus Curiae CropLife America (CLA)[1] is a national, not-for-profit trade association representing companies that develop and sell crop-protection and pest-management products in the United States.[2] CLA's member companies produce most of the crop-protection and pest-management products regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, and Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended, 21 U.S.C. § 346a. CLA represents its members' interests by, among other things, monitoring federal agency actions and related litigation of concern to the crop-protection and pest-control industry, and participating in such actions as appropriate.

CLA urges the Court to grant rehearing to prevent the harm that the panel opinion would cause CLA's members and the public. The panel opinion is inconsistent with both precedent and FIFRA's statutory framework. Revising the

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[1] This brief is submitted with an accompanying motion seeking leave to file as required by Circuit Rule 29-2. No counsel for any party in this case authored this brief in whole or in part. No party, party's counsel, or any person other than *amicus* and its members has contributed money to the preparation or submission of this brief.

[2] CLA has a committee, Responsible Industry for a Sound Environment (RISE), which serves as a national association to promote intelligent use of pesticides in urban and other non-agricultural areas.

panel majority's opinion will benefit the public and will not adversely impact human health or the environment.

The panel majority summarily directs EPA to cancel the registration of every pesticide product containing chlorpyrifos without consideration for how this action would harm pesticide manufacturers, users and the public, or whether the tolerances that Petitioners sought to revoke are relevant to every registration. CLA disputes that the Court has jurisdiction or an adequate basis in the record to enter such an order. If EPA ultimately were to determine that any chlorpyrifos registration would need to be cancelled, such an action could not be accomplished in the way the panel majority prescribed: by circumventing the procedures Congress required to ensure that pesticide cancellation decisions are not made unless and until these harms and the best science available are properly vetted.

If rehearing is not granted, chlorpyrifos would suddenly disappear from the marketplace, harming the public in multiple ways. If FIFRA's procedures are not respected, pesticide manufacturers, their distribution chain, and users will face a chaotic set of circumstances. Replacing chlorpyrifos—or any other pesticide—with a substitute, even *if* replacement is determined to be necessary, is not a turnkey action. It is a complex matter that involves many stakeholders who have not been heard as Congress intended.

For instance, leaving the panel opinion in place would suddenly deprive public health authorities of an important tool for controlling mosquitoes and other disease vectors. These harms must be considered—and mitigated or avoided—under the risk-benefit standard and procedures Congress specified in FIFRA.

CLA does not agree with the Panel's merits ruling. But even if that ruling were appropriate, it has no relevance to chlorpyrifos products offered for public health or other non-food uses. Non-food uses do not require tolerances and are subject only to regulation under FIFRA, not the FFDCA.

As stated in Respondents' petition, rehearing is warranted because the panel decision conflicts with the decisions of this Court and the Supreme Court of the United States. At the very least, rehearing will provide an opportunity to bring the panel majority's decision in line with FIFRA, which provides valuable protections for CLA's members and the public. During rehearing and in the event the Court reverses the panel majority, FIFRA's comprehensive registration review, cancellation, and suspension provisions will ensure that chlorpyrifos's safety—and any risk it may present—remains the subject of close scrutiny.

ARGUMENT

I. The Panel Opinion Orders EPA to Bypass Cancellation Procedures Intended to Protect CLA's Members and the Public

The panel majority's directive that EPA "cancel all registrations for chlorpyrifos within 60 days," Slip Op. at 32, disregards "the rigorous cancellation

process Congress provided for in [FIFRA]." *Reckitt Benckiser Inc. v. EPA*, 762 F. Supp. 2d 34, 42 (D.D.C. 2011). Neither FIFRA nor the FFDCA authorize bypassing these procedures.

If rehearing is not granted, all chlorpyrifos registrations would be cancelled without consideration for how this action would affect the agricultural sector, public health authorities, the general public, and chlorpyrifos registrants. FIFRA's cancellation procedures, set forth in Section 6(b), 7 U.S.C. § 136d(b), and 40 CFR Part 164, provide due process for registrants—CLA's members—whose registrations may be challenged. Congress also crafted the cancellation process to ensure that cancellation decisions are scientifically sound and account for impacts to a diverse range of stakeholders—growers, agricultural workers, public health authorities, distributors, retailers, and the general public—who rely on safe, effective pesticide products.

To the extent any chlorpyrifos registration needs to be cancelled, which CLA does not agree is the case, this should not be done by ignoring FIFRA's cancellation process. Foregoing these procedures would create a series of challenges that will disadvantage CLA's members and the users of their products. Taking a pesticide off the market, when properly determined necessary, cannot be accomplished by flipping a switch. At a minimum, time for planning is needed to arrange for orderly transitions that protect users and others in the distribution

channels, and to permit users to identify substitutes, if any are available, that can be deployed to meet each user's pest control needs.

A. Congress Dictated the Procedures for Cancelling FIFRA Registrations

The panel majority requires EPA to cancel all chlorpyrifos registrations without observing the FIFRA processes designed to ensure that these decisions are factually sound and do not cause unnecessary harm. FIFRA's cancellation process begins if EPA finds that a pesticide either (1) no longer complies with FIFRA's "registration standard"—*i.e.* the pesticide causes "unreasonable adverse effects on the environment"[3]—or (2) otherwise fails to comply with FIFRA. 7 U.S.C. § 136(bb). Cancellation decisions must involve weighing "the benefits as well as the risks [of a pesticide's] use, including the economic consequences of [cancellation]." *Love v. Thomas*, 858 F.2d 1347, 1357 (9th Cir. 1988).[4] If EPA finds that a pesticide no longer meets the registration standard, it may either issue

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[3] FIFRA defines "unreasonable adverse effects on the environment" to mean either: (1) "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" or (2) "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [FFDCA] section 408." *Id.* § 136(bb).

[4] Although *Love* concerned suspension of a registration, its description of what EPA must consider applies to cancellation. Both cancellation and suspension decisions require EPA to act under the same registration standard. *See* 7 U.S.C. §§ 136(*l*) and 136d(b), (c)(1).

(a) a notice of intent to cancel the registration or (b) a notice to hold a hearing on whether cancellation is warranted. *Id.* § 136d(b)(1)-(2).

1. Procedures Protecting Public Interests

Section 6(b)'s procedures ensure that cancellation decisions are consistent with FIFRA's registration standard and consider the interests of all potentially affected stakeholders. FIFRA directs EPA to assess "the impact [of cancellation] on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." 7 U.S.C. § 136d(b). Congress further required that EPA forward this analysis, along with its draft cancellation notice, to the U.S. Department of Agriculture (USDA) for comment at least 60 days before issuing any cancellation notice.[5] *Id.* These procedures ensure that any cancellation decision takes into consideration its potential impact on farmers and consumers.[6]

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[5] If USDA does not provide EPA with comments within thirty days of receipt of EPA's agricultural impact analysis and proposed cancellation notice, EPA may issue the cancellation notice before the end of the sixty-day period referenced above. 7 U.S.C. § 136d(b).

[6] *Merrell v. Thomas*, 807 F.2d 776, 780-81 (9th Cir. 1986) (USDA comment process "reflects the need [under FIFRA] to balance environmental and agricultural impacts."); *McGill v. EPA*, 593 F.2d 631, 635 (5th Cir. 1979) (cancellation procedures "were also designed to assure that the economic interests of farmers and other consumers would be fully considered before any pesticide was withdrawn from the market").

When a pesticide, like chlorpyrifos, has important public health applications,[7] EPA must give the Department of Health and Human Services (HHS) an opportunity to review and comment on any proposed cancellation notice. 7 U.S.C. § 136d(b). EPA also must submit any notice of cancellation for review by the Scientific Advisory Panel (SAP), a multidisciplinary panel of experts nominated by the National Institutes of Health and the National Science Foundation. 7 U.S.C. § 136w(d). These reviews provide assurances that EPA will not cancel a pesticide registration without subjecting its scientific analysis to independent review and considering potential public health risks resulting from taking a pesticide off the market.

[7] Chlorpyrifos is one of the few active ingredients incorporated into products registered for use to control pests that act as disease vectors, including adult mosquitoes in outdoor residential and recreational areas. *See* McAllister Decl. ¶¶ 7-8, attached at A4; *see also, e.g.*, EPA Registration No. 8329-18, Mosquitomist TWO U.L.V, *available at* https://www3.epa.gov/pesticides/chem_search/ppls/008329-00018-20170420.pdf. Mosquitos and other pests may develop resistance to active ingredients if products containing them are used too frequently. McAllister Decl. ¶ 8, attached at A4; EPA, Pesticide Registration Notice 2017-1, *Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling* at 4 (Aug. 24, 2017). Thus, elimination of any of the few active ingredients that provide mosquito control can severely impact disease control efforts.

2. Procedural Protections for Registrants

FIFRA's cancellation provisions also protect the rights of registrants, which stand to lose the right to sell a valuable product if EPA cancels a cancellation.[8] At the conclusion of the inter-agency review process outlined above, EPA issues a notice of cancellation. 7 U.S.C. § 136d(b). The notice becomes final and the cancellation effective after thirty days unless the registrant or another affected person requests a hearing. *Id.* Such a hearing provides *de novo* review of a proposed cancellation's merits before an administrative law judge (ALJ), and scientific questions may be referred to a committee of the National Academy of Sciences. *See id.* § 136d(d); 40 C.F.R. Part 164.

The hearing decision is subject to Environmental Appeals Board review. 40 C.F.R. §§ 164.100-.111. If the Environmental Appeals Board upholds the cancellation decision, EPA may issue a final cancellation order, subject to review in the appropriate U.S. Court of Appeals. 7 U.S.C. § 136n(b).

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[8] Registrants have property rights in their pesticide registrations that should not be extinguished without sufficient opportunity to contest individual cancellation decisions. *See Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("A FIFRA registration is a product-specific license"); *Ctr. for Biological Diversity v. EPA*, No. 11-cv-00293-JCS, 2013 WL 1729573, at *6 (N.D. Cal. Apr. 22, 2013) (registrants "have property and financial interests in the[ir] registrations."); *see also, e.g.*, *Bell v. Burson*, 402 U.S. 535, 539 (1971); 5 U.S.C. § 558(c) (licenses cannot be withdrawn or revoked without notice and "the opportunity to demonstrate or achieve compliance with all lawful requirements.").

B. The Panel's Order Requires EPA to Disregard Congressionally-Mandated Cancellation Procedures

1. The Panel's Order Precludes Following FIFRA's Cancellation Procedures

The panel opinion orders EPA to cancel every chlorpyrifos registration without assessing—as Congress required—how cancellation would impact the public and without respecting individual registrants' rights. The panel ordered EPA to "cancel all registrations … within 60 days." Slip Op. at 32. It made no reference to FIFRA's cancellation procedures, including the interagency review process that, among other things, provides EPA with information on how cancellation will impact the public. It also did so without acknowledging the distinction between food and non-food use registrations.[9]

The order also appears to foreclose registrants' ability—and right—to appeal any cancellation decision. Interagency review requires a minimum of thirty days (if the agencies and SAP provide no comments), and FIFRA affords registrants another thirty days from the date a notice of intent to cancel is issued to decide whether to appeal. *See* 7 U.S.C. §§ 136d(b), 136w(d). However, the panel opinion gives EPA just sixty days to complete the cancellation process, such that a

[9] Both food and non-food uses are entitled to protection under FIFRA's registration standard and cancellation procedures, even if these two classes of uses may be subjected to different standards of review. However, only pesticides that may result in residues on food require tolerances or exemptions from tolerance to be registered. Thus, revocation of tolerances is irrelevant to non-food use registrations. *See* Section II *infra.*

registrant's first opportunity to obtain any review—a hearing before an ALJ—would begin just as the Court's deadline expires.

2. The Panel Opinion's Relief Is Inconsistent with FIFRA and the FFDCA

By foregoing these procedures, the panel opinion is contrary to FIFRA's directive that Section 6(b) contains the "process that EPA *must* follow when it … cancel[s] … a registration." *Reckitt Benckiser*, 762 F. Supp. 2d at 42; *see also Defenders of Wildlife v. Administrator*, 882 F.2d 1294, 1299 (8th Cir. 1989) ("[w]hen Congress has established a special statutory review procedure [referring to FIFRA § 6], we generally treat that procedure as the exclusive means of review.") Accordingly, courts generally refuse to permit litigants to obtain cancellations in a manner that bypasses Section 6(b) procedures.[10]

Courts have permitted claimants to avoid these procedures only in a limited circumstance not found here: when another statute authorizes independent relief outside FIFRA's confines. *See, e.g., Wash. Toxics Coalition v. EPA*, 413 F.3d

[10] *See Reckitt*, 762 F. Supp. 2d. at 43 (EPA cannot forego § 6(b) cancellation proceedings by bringing a misbranding action); *Ellis v. Bradbury*, No. C-13-1266, 2014 WL 1569271, at *7-8 (N.D. Cal. Apr. 18, 2014) (dismissing claims seeking to cancel or suspend registrations without invoking § 6 procedures); *see also Defenders of Wildlife v. Administrator*, 882 F.2d 1294, 1302 (8th Cir. 1989) (challenges to pesticide registrations under two wildlife protection statutes should have been made by "petition[ing] the EPA to cancel registrations or request other action.").

1024, 1034 (9th Cir. 2005) (FIFRA's suspension procedures do not operate to bar suits to enforce Section 7 of the Endangered Species Act).

No statute provides such authorization here. To the contrary, the FFDCA limits the remedy in this action to affirming or setting aside an EPA order denying the petition to revoke chlorpyrifos tolerances. *See* 21 U.S.C. § 346a(h)(2); *see also Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 21 (1979) ("where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it."). Thus, CLA concurs with Respondents' position that rehearing is also justified because the Court may not order the specific action that EPA may take (*e.g.*, revoking all tolerances); it may only remand to EPA for further consideration. *See* Pet. for Reh'g at 12-13.

Even more fundamentally, the FFDCA provides no basis for Petitioners to obtain a judgment directing EPA to cancel all registrations or bypass FIFRA's cancellation process. To the contrary, the FFDCA directs that any cancellation take place consistent with the procedures in FIFRA § 6(b). Whenever EPA issues a rule revoking a tolerance, the FFDCA directs the agency to "coordinate such action with any related necessary action under [FIFRA]." 21 U.S.C. § 346a(*l*)(1). Congress provided a clear directive: any cancellation decision related to revocation of a tolerance must proceed under FIFRA § 6(b).

C. Cancelling Chlorpyrifos Registrations Without Observing Procedural Safeguards Will Harm CLA's Members, Pesticide Users, and the Public

If the panel opinion stands, EPA would be unable to consider and take action to mitigate the impact that cancelling chlorpyrifos registrations will have on CLA members, users, and the public. Congress designed the Section 6(b) process described in Section I.A. to ensure that any cancellation decision is made only after weighing the impacts that terminating a registration will have on these diverse stakeholders. *See Love*, 858 F.2d at 1350.

By preventing EPA from assessing impacts, the panel opinion would also preclude EPA from obtaining the information it needs to develop a plan to mitigate economic, public health, and other harms resulting from cancelling registrations. Such a plan would typically involve EPA providing for sale and use of existing stocks of the pesticide. *See* 7 U.S.C. § 136d(a)(2). Among other factors, EPA would consider the economic losses that CLA members and others in the distribution channel would suffer, and potential environmental impacts (*e.g.*, of disposal) if existing stocks could not be sold or used. *See* EPA, *Existing Stocks of Pesticide Products; Statement of Policy*, 56 Fed. Reg. 29362, 29364 (June 26, 1991).

EPA would also consider—if not foreclosed from doing so by the panel opinion—whether cancelling chlorpyrifos registrations would leave users without

viable pest control solutions.[11] *See id.* Pesticide products are not readily interchangeable. McAllister Decl. ¶ 4, attached at A2. Each user considers her/his individual circumstances in determining which specific product will address the specific pest pressure the user is seeking to control. *See id.* In some circumstances, there may be no effective and viable alternative available to meet a specific requirement.

An alternative's viability as a substitute depends on the type of use at issue, the class(es) of pests against which the product's active ingredient is effective, and numerous case-specific factors. *Id.* Such factors include: (1) the particular use;[12] (2) identity and biology of the pest species (the species of insect, in the case of insecticides) for each particular use; (3) weather and climate conditions at time of application and afterward; (4) soil type of treated fields; (5) local crop cultural practices; (6) timing of application(s); (7) method of application(s); (8) avoidance of development of resistance among target pests; and the product's (9) environmental, (10) worker protection, (11) and general human health profiles. McAllister Decl. ¶ 5, attached at A2-A3.

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[11] The availability of alternatives and their attributes are also considered when EPA evaluates a pesticide's benefits under FIFRA's definition of "unreasonable adverse effects on the environment." *See supra* note 3.

[12] The active ingredient at issue here is registered for diverse food and non-food uses, including agricultural, human health/mosquito control, and turf and ornamental uses. *See* Walsh Decl. ¶ 5, Pet. for Reh'g at A57-A58.

Even if there is a product that fits a user's particular needs, it must be commercially available. *Id.* ¶ 6, attached at A3. This requires that: (1) the product be registered for use at both the federal and state levels; (2) the product be properly manufactured in a facility according to EPA requirements; (3) an appropriate facility with the capacity to make the needed amount of product be located and reserved; (4) the product be properly labeled in a facility according to EPA requirements; (5) the amount of product needed to satisfy commercial demand can be accurately predicted, taking into account predicted pest pressures; (6) the product can be safely and properly transported from the production site through the distribution channel (commonly to distributors and then to retailers, who must have the capacity to manage the new product(s)); and (7) the product arrive at a myriad of locations where different types of users (*e.g.*, agricultural, public health, and others) around the country can have access to their chosen products. *Id.*

Determining whether a commercially viable alternative product exists is a complex process involving many factors and actors under normal circumstances. *Id.* If rehearing is not granted, this process will be made exponentially more complex because neither EPA nor users will have sufficient time to find alternatives, assuming that they exist, or develop a plan for the use of existing stocks.

II. The Panel's Merits Holding Does Not Support Cancellation of Non-Food Registrations

This case arises from EPA's alleged failure to take action on a petition to revoke tolerances. Tolerances set the limit of chemical residue that may be found in food. No tolerance is needed when a use does not result in pesticide residue in or on food. As a result, petitioners' request to revoke chlorpyrifos tolerances relates only to registrations that require the challenged tolerances.

The panel majority's order contains no justification for cancelling non-food use registrations.[13] The majority's cancellation remedy will impact 79 registrations held by 20 different registrants. Walsh Decl. ¶ 5, Pet. for Reh'g at A57-A58. Of these, at least 28 are solely for non-food uses, and at least 45 additional registrations have both food and non-food uses. *Id.*

These non-food uses should not be cancelled because they have no relationship to the panel's merits ruling. The portion of the FIFRA registration standard referencing tolerances set under the FFDCA does not apply to non-food uses. *See* 7 U.S.C. § 136(bb)(2). Instead, these uses are evaluated only under FIFRA's risk-benefit standard. The panel majority's decision on the merits, which is based on *dietary* exposure to chlorpyrifos, has no impact on whether non-food

[13] CLA submits that the panel majority erred by ordering the cancellation of any registrations, and that the panel's cancellation order warrants rehearing for the reasons stated above and in Respondents' petition for rehearing. *See supra* at Section I.B; Pet. for Reh'g at 13-17.

registrations satisfy FIFRA's registration standard. *See id.* § 136(bb)(1); Pet. for Reh'g at 15-16; Yu-Ting Decl. ¶ 8, Pet. for Reh'g at A54.

The panel majority's overbroad directive to cancel non-food uses will, for instance, take away from public health officials important tools for use against disease-carrying insects.[14] Chlorpyrifos is one of the few active ingredients registered for use against adult mosquitoes, which are known vectors of human disease, such as the Zika and West Nile viruses. McAllister Decl. ¶ 7, attached at A4. It is an important tool in mosquito abatement programs in outdoor residential and recreational areas. *Id.* ¶ 8, attached at A4. Public health agencies use chlorpyrifos in rotation with products containing other active ingredients to prevent resistance from developing. *Id.* The demand for chlorpyrifos for use in mosquito control is substantial; enough chlorpyrifos product was sold over the past five years to support protective spraying of the equivalent of over 10 million acres of land per year. Bosarge Decl. ¶ 4, attached at A6.

[14] Additional examples of non-food chlorpyrifos uses include killing cockroaches in sewer manholes, controlling a variety of ticks and flies by applying ear tags to cattle, and managing cockroaches, flies, mites, and beetles in poultry barns. Summary cancellation of these and other non-food uses is unjustified by the panel majority's decision and FIFRA itself. McAllister Decl. ¶ 9, attached at A4.

III. Public Health and The Environment Are Protected

Chlorpyrifos will be the subject of uninterrupted, public, and science-based scrutiny and regulation in the event the Court grants rehearing and reverses the panel opinion. In particular, all chlorpyrifos products are undergoing FIFRA's statutorily-required "registration review"—a reevaluation of whether each product continues to meet FIFRA's registration standard

FIFRA requires products that have been approved for sale, including chlorpyrifos products, be (a) re-reviewed on a statutory schedule, 7 U.S.C. § 136a(g); and (b) that any cancellation, whether voluntarily or over the objections of the registrant(s) or others, takes into account (i) whether the pesticide meets FIFRA's registration standard, (ii) input from stakeholders, including registrants, others in the distribution channel, users, and members of the public, and (iii) input from USDA, HHS, and independent scientific experts. *Id.* §§ 136d(b), 136w(d). FIFRA also gives EPA authority to act quickly to "suspend" use of a product if it determines that the product poses "imminent" harm. *Id.* § 136d(c).

Registration review is a systematic analysis of existing and new information under the FIFRA risk-benefit standard. It requires EPA to determine what, if any, revisions to the terms and conditions of each registration should be made, including whether any use should be cancelled. *See* 40 C.F.R. §§ 155.40, 155.53; Yu-Ting Declaration ¶ 11, Pet. for Reh'g at A55.

If registration review results in EPA concluding that changes to chlorpyrifos registrations are necessary, the agency will transparently address the scope and timing of such changes. 40 C.F.R. § 155.58. Any proposed cancellations, if necessary, would be done consistent with Section 6(b), as described above. *See* 7 U.S.C. § 136a(g)(1)(A)(v).

If rehearing is granted, FIFRA mandates that the public registration review of chlorpyrifos proceed without interruption. Government agencies, independent scientific experts, agricultural and public health stakeholders, and the public all have meaningful opportunities to participate. In response to data and comments submitted by these stakeholders, EPA has the authority to act as needed to protect the public and the environment.

CONCLUSION

Congress created a system to ensure that no pesticide registration is cancelled without considering how this action will harm registrants, users, and the American people. The panel opinion sweeps too broadly by disregarding FIFRA's cancellation process and by ordering the cancellation of registrations not implicated by the panel's merits decision. Because these errors will harm CLA's members and other stakeholders, CLA joins Respondents in urging the Court to grant *en banc* and panel rehearing of the panel's August 9, 2018 decision.

Respectfully submitted,

October 4, 2018

s/ Kathryn E. Szmuszkovicz

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CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies that this brief complies with the type-volume limitation of Circuit Court Rule 29-2(c)(2) because it contains 4,176 words, excluding the parts of the brief exempted by the Federal Rule of Appellate Procedure 32(a)(7)(B)(iii), according to the count of Microsoft Word.

Undersigned counsel certifies that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionately spaced 14-point Times New Roman font.

Dated: October 4, 2018

s/ Kathryn E. Szmuszkovicz
Kathryn E. Szmuszkovicz

Attorney for Amicus Curiae
CropLife America

CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2018, I caused to be filed electronically the foregoing Brief of *Amicus Curiae* CropLife America in Support of Respondents' Petition for *En Banc* and Panel Rehearing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system, that all participants in this case are registered appellate CM/ECF users, and that service will be accomplished by the appellate CM/ECF system.

Dated: October 4, 2018

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ADDENDUM

Declaration of Ray S. McAllister..... A1

Declaration of Leanna Bosarge..... A5

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

League of United Latin American Citizens, et al., Petitioners, v. Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency; and U.S. Environmental Protection Agency, Respondents.	No. 17-71636

DECLARATION OF RAY S. MCALLISTER

I, Ray S. McAllister, am over 18 years of age, and I am competent to be a witness in this proceeding. I give this Declaration based on my own personal knowledge and experience from working in the pesticide industry, most recently as an employee of CropLife America.

1. I currently serve as Senior Director, Regulatory Policy, at CropLife America, a position I have held since 1989. My office is located at 1156 15th Street NW, Suite 400, Washington, DC 20005. In this role, I am responsible for regulatory policy development and coordination, working with member committees and government regulatory agencies.

2. I hold both an M.S. and a Ph.D. in Weed Science, which I received, respectively, from Utah State University and the University of Nebraska-Lincoln. I also hold an M.Ed. from Brigham Young University. I am a member of multiple professional societies and organizations, including the American Chemical Society and the Weed Science Society of America. I am also a member and serve on the advisory board of the North American Pollinator Protection Campaign.

3. In carrying out my responsibilities, I have gained familiarity with the practical aspects of the U.S. Environmental Protection Agency's oversight of pesticides and our members' activities, as well as the practical aspects of our members' compliance with requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as they work to meet the public's demands for their products.

4. Generally speaking, one pesticide product cannot be easily substituted for another. Whether one pesticide may be substituted for another depends on the particular type of use (e.g., crop, non-crop) that is involved; the class(es) of pests against which the product's active ingredient is effective; and numerous case-specific factors.

5. The case-specific factors referenced in the preceding paragraph include: (a) the specific use; (b) identity and biology of the pest species (the species of insect, in the case of insecticides) for each particular use; (c) weather

and climate conditions at time of application and afterward; (d) soil type of treated fields; (e) local crop cultural practices; (f) timing of application(s); (g) method of application(s); (h) avoiding the development of resistance among target pests; and the product's (i) environmental, (j) worker protection, and (k) general human health profiles.

6. Even if a pesticide might be effective as a substitute for another, it must be commercially available. Commercial availability means that: (a) the product is registered for use at both the federal and state levels; (b) the product must be properly manufactured in a facility according to EPA requirements; (c) an appropriate facility with the capacity to make the needed amount is located and reserved; (d) the product must be properly labeled in a facility according to EPA requirements; (e) the amount of product needed to satisfy commercial demand must be accurately predicted, taking into account predicted pest pressures; (f) the product can be safely and properly transported from the production site through the distribution channel (commonly to distributors and then to retailers, who must have the capacity to manage the new product(s)); and (g) the product can arrive at the myriad of locations for different types of uses (e.g., agricultural, public health, and others) around the country, in a timely manner, where different types of users have access to their chosen product. As a result, obtaining a substitute product is a complex endeavor.

7. Chlorpyrifos is one of the few active ingredients registered for use against adult mosquitos, which are known vectors of human disease, such as the Zika and West Nile Viruses.

8. Mosquitos and other pests may develop resistance to pesticide active ingredients if products containing them are used too frequently. As a result, chlorpyrifos plays an important role in mosquito abatement programs in outdoor residential and recreational areas, particularly when used in rotation with other active ingredients to avoid resistance issues.

9. In addition to being used to control mosquitos, chlorpyrifos is used to kill cockroaches in sewer manholes, to control a variety of ticks and flies by applying ear tags to cattle, and to manage cockroaches, flies, mites, and beetles in poultry barns.

I hereby declare and affirm, subject to the penalties of perjury, that the foregoing statement is true and correct to the best of my knowledge, information, and belief.

Dated: October 3, 2018

Ray S. McAllister

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

League of United Latin American Citizens, et al., Petitioners, v. Andrew Wheeler, Acting Administrator of the U.S. Environmental Protection Agency; and U.S. Environmental Protection Agency, Respondents.	No. 17-71636

DECLARATION OF LEANNA BOSARGE

I, Leanna Bosarge, am over 18 years of age, and I am competent to be a witness in this proceeding. I give this Declaration based on my own personal knowledge and experience from working for Control Solutions Inc. (CSI), a member of the ADAMA Group, headquartered in Pasadena, Texas.

1. I am Director, Regulatory Affairs for CSI and have held that position for approximately three years. In this role, I am responsible for managing relationships between our company and regulatory agencies at the federal and State level and working with CSI's customers to assure that our products serve their commercial needs.

2. In the course of performing my duties for CSI, I have gained familiarity with our sales figures and other commercial matters.

3. Another company in the ADAMA Group holds a registration granted by the U.S. Environmental Protection Agency that allows CSI to sell and distribute Pyrinex Chlorpyrifos Insecticide (EPA Reg. No. 11678-58), a product containing chlorpyrifos that is used by another company to formulate "end-use" mosquito control adulticides.

4. I have reviewed CSI's sales reports for the past 5 years, which I believe are representative of our historic annual sales of Pyrinex Chlorpyrifos Insecticide, and identified a customer who has purchased this product for formulation of end-use mosquito control adulticides. Based on the quantity of Pyrinex Chlorpyrifos Insecticide sold, the concentration of chlorpyrifos stated on the EPA-approved product labels for CSI's customer's two mosquito adulticide end-use products formulated from Pyrinex Chlorpyrifos Insecticide, and the maximum amount of those two end-use products that may be applied consistent with their EPA-approved product labels, I estimate that CSI sold sufficient Pyrinex Chlorpyrifos Insecticide to provide for the mosquito adulticide treatment of more than 10 million acres per year of residential, recreational and other non-agricultural property.

I hereby declare and affirm, subject to the penalties of perjury, that the foregoing statement is true and correct to the best of my knowledge, information, and belief.

Dated: October 4, 2018

Leanna Bosarge

Form 8. Certificate of Compliance Pursuant to 9th Circuit Rules 28.1-1(f), 29-2(c)(2) and (3), 32-1, 32-2 or 32-4 for Case Number 17-71636

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Signature of Attorney or Unrepresented Litigant: s/ Kathryn E. Szmuszkovicz

Date: October 4, 2018

("s/" plus typed name is acceptable for electronically-filed documents)

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